K111681

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JAN 19 2012

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

1. Submitted by: Puritan Medical Products Co LLC
   Contact person: William M. Young
   Date of preparation: December 19, 2011

2. Trade Name of Device: Histobrush Model 2188

   Common name: Cervical cytology brush
   Classification name: Cytological endocervical brush

3. Predicate Devices: Histobrush, Spectrum Companies, K874604
   Cell Collecting Brush, Anderson Winn, K924908

4. Device description: The Puritan Histobrush consists of nylon bristles secured by stainless steel to a plastic handle. The device is used to obtain endocervical samples for Pap smear cytology. The device is for single use only and is non-sterile.

5. Indications for use: To obtain endocervical cells for Pap smear cytology test.

6. Intended use: The Puritan Histobrush is used to obtain cervical samples for transfer to a microscope slide or specimen preservation vial.

7. Comparison of technological characteristics to predicates:

	Histobrush ® (Model 2188)	Predicate device
Tip material	Nylon	Nylon
Tip length (inches)	0.750	0.600
Tip diameter maximum/minimum (inches)	0.250/0.200	0.280/0.120
Twisted wire	Stainless steel 304	Stainless steel 304
Handle material	Polystyrene	Polystyrene
Overall length (inches)	8	6

8. Discussion of non-clinical tests

Non-clinical testing included: biocompatibility, tensile strength of brush fibers, force to remove fibers from wire, and force to remove wire from handle. The results of the testing demonstrate substantial equivalence to predicate cervical cytology brushes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. William Young
Vice President, Quality Systems
Puritan Medical Products Co LLC
31 School Street
GUILFORD MA 04443

JAN 19 2012

Re: K111681
Trade Name: Histobrush® (Model 2188)
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HHT
Dated: December 19, 2011
Received: December 21, 2011

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111681

Device Name: Histobrush® Model 2188

Indications for Use:

To obtain endocervical cells for Pap smear cytology test

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111681